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PATENT**REMARKS**

This paper is being filed in response to the Office Action dated March 20, 2003 that was issued in connection with the above-identified patent application. Applicants also enclose herewith a Petition for Extension of Time pursuant to 37 C.F.R. §1.136(a), a Notice of Appeal, a Supplemental Information Disclosure Statement, a Form PTO-1449, and authorization for the fees required under 37 C.F.R. §§ 1.17(a)(3), 1.17(b), and 1.17(p), respectively. Applicants respectfully request reconsideration of the instant application in view of the amendments and remarks presented herein.

Claims 1, 4, 7, 8, 9, 18-22, 24-27, and 36 are pending in the instant application. Claims 1, 9, 20, 21, 24, and 26 have been amended herein. These amendments are supported by the application as originally filed at, *inter alia*, page 2, lines 6-16 and 34-36 and, therefore, do not constitute new matter. Claims 4, 8 and 19 have been cancelled without prejudice. New claim 37 has been added. Claim 37 is supported by the application as originally filed at, *inter alia*, page 2, lines 1-16 and original claims 3-4 and, therefore, does not constitute new matter. Therefore, upon entry of the instant Amendment, claims 1, 7, 9, 18, 20-22, 24-27, 36 and 37 will be pending.

As a preliminary matter, Applicants thank the Examiner for kindly withdrawing all of the earlier rejections under 35 U.S.C. § 112. Applicants also thank the Examiner for withdrawing all of the earlier rejections under 35 U.S.C. §§ 102 and 103.

Claims Are in Proper Form

Claim 4 has been objected under 37 C.F.R. § 1.75(c) as allegedly being in improper dependent form for failing to limit the subject matter of a previous claim. Claim 4 has

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been cancelled rendering this objection moot. Claim 37 has been added in independent form. Therefore, Applicants respectfully request withdrawal of this objection.

Claims Are Drawn to Statutory Subject Matter

Claim 4 has been rejected under 35 U.S.C. § 101 as allegedly being drawn to subject matter that does not sufficiently evidence the hand of man. Claim 4 has been cancelled rendering this rejection moot. Claim 37 has been added in independent form and recites the phrase "An isolated antigenic fragment." Applicants, therefore, respectfully request withdrawal of the instant rejection.

Specification Provides Ample Antecedent Basis for Claimed Subject Matter

Claims 1, 4, 7-9, 18-22, and 24-27 have been rejected under 35 U.S.C. § 112, first paragraph as allegedly being drawn to subject matter that was not described in the specification in such a way as to reasonably demonstrate to one of ordinary skill in the art that Applicants were in possession of the claimed invention. The Examiner has alleged that the limitation in claim 1 relating to SEQ ID NOS:3-5 constitutes new matter.

Applicants traverse this rejection and assert that claims 1, 7, 9, 18, 20-22, 24-27, 36 and 37 are drawn to subject matter that is amply described in the specification. Claims 4, 8, and 19 have been cancelled rendering this rejection moot as to these claims. Claim 37 has been added in independent form. Claims 1, 7, 9, 18, 20-22, 24-27, 36 and 37 do not recite SEQ ID NOS:3-5. Therefore, Applicants respectfully request withdrawal of the instant rejection.

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Claims 1, 4, 8, 9, 21, 22, and 24-27 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. The Examiner has alleged that the term "Xaa" in claim 1 is unclear. The Examiner has also alleged that claim 9 is unclear with respect to the antecedent for the term "protein fragment." The Examiner has alleged that claims 4, 8, 21, 22, and 24-27 are indefinite since they depend on allegedly indefinite claims.

Applicants traverse these rejections and assert that the claims, as amended herein, are clear and definite. Applicants assert that the meaning of the term "Xaa" would be clear to one of ordinary skill in the art in view of the common usage of this term in the scientific literature and in Applicant's disclosure and Sequence Listing. Nevertheless, Applicants have amended claim 1 to recite the phrase "wherein Xaa is an unknown amino acid" as suggested by the Examiner. In view of the common usage and usage in Applicant's specification, this amendment does not narrow the scope of the claims in any way. Applicants respectfully request withdrawal of this rejection.

Claims Are Novel over the Cited Documents

Claims 1, 4, 8, 9, 21, 22, and 24-27 have been rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 6,100,380 issued to Green LR et al. on August 8, 2000 (hereinafter "Green") as evidenced by U.S. Patent No. 6,436,391 issued to Foster CR et al. on April 20, 2002 (hereinafter "Foster"). The Examiner has stated that claim 1 has been included in this rejection only to the extent that claim 4 includes the limitation "claim 1." The Examiner has alleged that Green discloses a therapeutic or prophylactic immunomodulating Gly-Lys

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dipeptide preparation in saline. The Examiner has alleged that the dipeptide of Green "serves as a fragment of the instantly recited SEQ ID NO:2." See Office Action dated March 20, 2003, section 32, second paragraph. In addition, the Examiner has alleged that Green discloses that a pentapeptide with the sequence TAEKK elicited an immune response in fish. Lastly, the Examiner has alleged that the interferon coadministered with the Green's dipeptide is an adjuvant as allegedly shown by Foster.

Applicants traverse these rejections and assert that the instant claims are novel over Green and Foster. Claims 4 and 8 have been cancelled rendering this rejection moot as to these claims. Since the Examiner has stated that claim 1 was included in this rejection only to the extent that claim 4 includes the limitation "claim 1", this rejection is also moot with respect to claim 1 and all of its dependent claims. Indeed, neither Green nor Foster teach a protein comprising an N-terminal amino acid sequence of SEQ ID NO:2 and, therefore, fail to anticipate claim 1. Therefore, Applicants respectfully request affirmation that this rejection is moot with respect to claim 1 or, in the alternative, withdrawal of this rejection as to claim 1.

New claim 37 recites the phrase "isolated antigenic fragment." Applicants respectfully assert that anyone of ordinary skill in the art would recognize that a dipeptide is too small to be antigenic. The minimum peptide length to trigger an immune response is generally believed to be about 5 to 8 amino acids. In fact, it appears to be the Examiner, not Green, that claims that the EK dipeptide is antigenic. Green discloses that the EK dipeptide was administered to mice no earlier than 15 hours prior to challenge. See Green, col. 21, lines 7-11. One skilled in the art would recognize that, even if the dipeptide were long enough to elicit an immune response, this time period is too short to stimulate either a T-cell mediated or humoral immune response and Green makes no assertion to the contrary. Thus, Green's EK dipeptide is

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not antigenic as recited in instant claim 37. In addition, Applicants assert that the TAEK pentapeptide of Green is irrelevant since the instant claims do not recite this sequence.

New claim 37 also recites the phrase "wherein said fragment comprises an N-terminal amino acid sequence of [SEQ ID NO:2]." Neither Green nor Foster teach such a protein fragment and, therefore, fail to teach each and every element of claim 37. Accordingly, Applicants respectfully request withdrawal of the instant rejection.

Claims Are Non-Obvious over the Cited Documents

Claims 1, 4, 8, 9, 19, 20, and 36 have been rejected under 35 U.S.C. § 103(a) as allegedly obvious over Green. The Examiner has stated that claim 1 has been included in this rejection only to the extent that claim 4 includes the limitation "claim 1." The Examiner has acknowledged that Green does not teach kits, but has alleged that assembling a kit would have been obvious to one of ordinary skill in the art.

Applicants traverse these rejections and assert that the instant claims are novel over Green and Foster. Claims 4, 8, and 19 have been cancelled rendering this rejection moot as to these claims. Since the Examiner has stated that claim 1 was included in this rejection only to the extent that claim 4 includes the limitation "claim 1", this rejection is also moot with respect to claim 1 and all of its dependent claims. Indeed, Green and Foster do not teach a protein comprising an N-terminal amino acid sequence of SEQ ID NO:2 and, therefore, fail to anticipate or render obvious the subject matter of amended claim 1. Therefore, Applicants respectfully request affirmation that this rejection is moot with respect to claim 1 or, in the alternative, withdrawal of this rejection as to claim 1.

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With respect to new claim 37, Green's EK dipeptide, as noted in the foregoing section, is too short to be antigenic and does not comprise the 19 amino acid sequence of SEQ ID NO:2. Therefore, Green fails to teach or suggest each and every element of instant claim 37. Applicants, therefore, respectfully request withdrawal of this rejection.

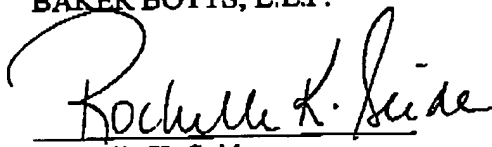
Conclusion

In summary, the claims, as amended herein fully comply with the formal requirements and are novel and nonobvious over Green and Foster, whether considered alone or in combination. In view of the foregoing remarks, Applicants believe that the claims are in condition for allowance and respectfully request prompt favorable action.

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Attorneys for Applicants hereby authorize the Commissioner to charge the fees required under 37 C.F.R. §§ 1.17(a)(3), 1.17(b), and 1.17(p) to Deposit Account No. 02-4377. No other fee is believed to be required in connection with this submission. Nevertheless, the Commissioner is hereby authorized to charge any other fees occasioned by this submission to Deposit Account No. 02-4377. Please credit any overpayment of fees associated with this filing to the above-identified deposit account. A duplicate of this page is enclosed.

Respectfully submitted,
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Enclosures